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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,600

02/23/2004

Bruce W. Kneller

BKNL-001-101

3185

75436

7590

05/15/2009

MORSE, BARNES-BROWN & PENDLETON, P.C.

ATTN: IP MANAGER

RESERVOIR PLACE

1601 TRAPELO ROAD, SUITE 205

WALTHAM, MA 02451

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/785,600	<b>Applicant(s)</b> KNELLER, BRUCE W.	
	<b>Examiner</b> Barbara P. Badio	<b>Art Unit</b> 1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-31,34 and 35 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-31,34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/11/2009</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

2. The rejection of claim 33 under 35 USC 112, first paragraph, scope of enablement is made moot by the cancellation of the instant claim.
3. The rejection of claims 27-31, 34 and 35 under 35 USC 112, first paragraph, scope of enablement is withdrawn.
4. The rejection of claims 32 and 33 under 35 USC 112, second paragraph, as being indefinite is made moot by the cancellation of the instant claims.
5. The rejection of claims 27-31, 34 and 35 under 35 USC 112, second paragraph, as being indefinite is withdrawn.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 21, 22, 25 and 26 under 35 USC 102(b) over Joska et al. (Collection of Czechoslovak Chemical Comm., 1961) is withdrawn.

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**7. The rejection of claims 21, 22 and 25 under 35 USC 102(b) over Marwah et al. (Steroids, 2001) is withdrawn.**

***Claim Rejections - 35 USC § 103***

**8. The rejection of claims 32 and 33 under 35 USC 103(a) over Joska et al. (Collection of Czechoslovak Chemical Comm., 1961), Marwah et al. (Steroids, 2001), Lardy et al. (US 5,506,223) and Pauza et al. (US 5,885,977) in combination is made moot by the cancellation of the instant claims.**

**9. The rejection of claims 21-31, 34 and 35 under 35 USC 103(a) over Joska et al. (Collection of Czechoslovak Chemical Comm., 1961), Marwah et al. (Steroids, 2001), Lardy et al. (US 5,506,223) and Pauza et al. (US 5,885,977) in combination is maintained.**

Applicant argues Joska et al. and Marwah et al. do not disclose the currently claimed modified  $\Delta 5$ -androstene compounds and Lardy et al. and Pauza et al. do not correct this defect. Accordingly, applicant argues the combination of references fails to teach or suggest the claimed invention because the combination fails to teach or suggest all elements of the invention. Applicant's argument was considered but not persuasive for the following reasons.

First, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

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208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Each of the cited references teaches  $\Delta$ 5-androstene compounds and derivatives thereof. Both Joska and Marwah teach a tetrahydropyranol ether derivative, i.e., 3-tetrahydropyranol ether. Each of Lardy and Pauza teaches derivatives that are readily metabolized in vivo to the parent compound. Lardy also teaches derivatives "wherein **one or more** of the hydroxyl or keto substituents is a group convertible thereto by hydrolysis" (see col. 2, lines 23-39). The art teaches (a) ethers as prodrugs that can be readily hydrolyzed in vivo and (b) the use of prodrugs to increase bioavailability as well as reduce side effects of drugs. Based on the knowledge in the art and the teachings of the cited prior art, making ether derivatives of  $\Delta$ 5-androstene compounds, such as tetrahydropyranol ether derivatives, would have been obvious to the skilled artisan in the art at the time of the present invention. As noted in the previous Office Action, the increase bioavailability and reduction in side effect(s) would provide the motivation needed.

For these reasons and those given in the previous Office Action, the rejection of claims 21-31, 34 and 35 under 35 USC 103(a) over Joska et al. (Collection of Czechoslovak Chemical Comm., 1961), Marwah et al. (Steroids, 2001), Lardy et al. (US 5,506,223) and Pauza et al. (US 5,885,977) in combination is maintained.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/  
Primary Examiner, Art Unit 1612